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Laura A Vogel

Michael J Mancuso
Bryan S Wade
Aaron L Schwartz
Michael G Penn*
Shannon A Carroll*
Wesley W Jones*
Matthew E Kelley*
Nicole R Kramer+

Registered Patent Agents•
Karen R Markowicz
Nancy J Leith
Matthew J Dowd
Katrina Yujan Pei Quach
Bryan L Skelton
Robert A Schwartzman
Teresa A Colella
Jeffrey S Lundgren
Victoria S Rutherford

Michelle K Holoubek
Simon J Elliott
Julie A Heider
Mita Mukherjee
Scott M Woodhouse
Christopher J Walsh
Liliana Di Nola-Baron
Peter A Socarras
Jeffrey Mills

Of Counsel
Kenneth C Bass III
Evan R Smith
Marvin C Guthrie

*Admitted only in Maryland
+ Admitted only in Virginia
•Practice Limited to Federal Agencies

October 5, 2005

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Citizen Petition Concerning Pending New Drug Application
For PATANASE® (Olopatadine Hydrochloride Nasal Spray)

Dear Sir/Madam:

We are hereby submitting the enclosed Citizen Petition concerning the proposed trade name PATANASE®, which is currently part of a pending new drug application for olopatadine hydrochloride nasal spray. In accordance with 21 C.F.R. §10.30, this original Citizen Petition is accompanied by five (5) copies thereof; it is respectfully requested that one copy be stamped with the date of receipt thereof by the U.S.F.D.A., and returned to the undersigned in the accompanying self-addressed stamped envelope.

Sincerely,

Jorge Goldstein, Ph.D., Esq.
Brian J. Del Buono, Ph.D., Esq.

cc: Badrul Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Drug Products
HFD-570

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CITIZEN PETITION

The undersigned submits this petition under the Federal Food, Drug, and Cosmetic Act (including sections 502 and 505 thereof) and 21 C.F.R. § 10.30 to request the Commissioner of Food and Drugs to refrain from accepting the proposed trade name PATANASE® as part of a pending new drug application for olopatadine hydrochloride nasal spray.

A. ACTION REQUESTED

This petition requests the Commissioner of Food and Drugs to refrain from accepting the proposed trade name PATANASE® as part of a pending new drug application ("NDA") for an olopatadine hydrochloride nasal spray submitted by Alcon, Inc. ("Alcon"). If Alcon declines to propose a different, acceptable trade name, this petition requests the Commissioner of Food and Drugs to refuse to approve the NDA.

B. STATEMENT OF GROUNDS

In a press release dated April 21, 2005, Alcon publicly announced that it had submitted, during the first quarter of 2005, a new drug application to FDA for olopatadine hydrochloride nasal spray under the proposed trade name PATANASE® and that the NDA had been accepted for filing. To the best of our knowledge and belief, the NDA is currently under review by the Center for Drug Evaluation and Research, Office of New Drugs. Accordingly, the proposed trade name PATANASE® is subject to review at this time.

FDA reviews proposed trade names submitted as part of new drug applications under its statutory authorities and implementing regulations. A primary focus of this review is the

assurance of safety by the avoidance of medication errors. Under 21 C.F.R. § 201.10(c), the labeling of a drug may be misleading by reason (among other reasons) of:

> (5) Designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient.

Confusion regarding drug names that may look similar or may sound similar can lead to medication dispensing errors and to significant safety concerns.

The Office of New Drugs in consultation with the Office of Drug Safety, Division of Medication Errors and Technical Support, reviews proposed proprietary names for "look-alike" and/or "sound-alike" similarities to proprietary or established names of drug products that are already approved and/or on the market. If this review indicates that the new proposed trade (proprietary) name would create unacceptable safety concerns, the review division typically requests the NDA sponsor to propose a new name. Even if an initial review has indicated that the proposed name may be tentatively acceptable, the trade name is not considered approved, under standard agency procedures, until the NDA receives final approval. Review of the new proposed trade name is thus appropriate at any time prior to NDA approval. If the NDA sponsor were to refuse to change an unacceptable proposed trade name, the agency may refuse to approve the NDA in accordance with agency regulations. 21 C.F.R. § 314.125(b)(6), (8).

The proposed trade name PATANASE® could potentially be confused with a number of existing product trade names. The following trade names of marketed pancreatic enzyme drug products exhibit significant "sound-alike" and/or "look-alike" similarities to the proposed name PATANASE®:

Panokase
Pancrease
Panase
Paltrase
Palipase
Protilase
Papase

Each of these existing trade names (except Protilase) begins with the same "Pa-" look and sound as PATANASE®, and each ends with the same "-ase" look and sound. Panokase, Pancrease and Panase each combine the initial "Pa-" element with the "-n" element, which is also present in the "Patan" portion of PATANASE®. Paltrase combines the initial "Pa-" element with a middle "lt" element; PATANASE® also has an initial "Pa-" combined with a middle "t." Similarly, Palipase has an initial "Pa-" combined with a middle "l," which may be readily confused with a middle

"t" particularly in written prescriptions. Protilase begins with a "P," includes a middle "t", and ends with an "-ase", as does PATANASE®. It is clear there is substantial potential for confusion, in both written and oral prescriptions, between PATANASE® and one or more of these products.

A patient who is prescribed PATANASE® but mistakenly receives a pancreatic enzyme product will not only fail to be treated for seasonal allergic rhinitis but, more significantly, will be exposed to the significant side effects of the pancreatic enzymes. These include potentially life-threatening allergic reactions and other serious side effects such as blood in the urine, severe stomach cramps or diarrhea, and trouble breathing. Additional potential side effects of pancreatic enzymes include constipation, nausea, rectal irritation, and rash.

A patient who is prescribed a pancreatic enzyme product but mistakenly receives PATANASE® will fail to be treated for pancreatic insufficiency. When pancreatic insufficiency is severe, malabsorption (impaired absorption of nutrients by the intestines) may result, leading to deficiencies of essential nutrients and the occurrence of loose stools containing unabsorbed fat (steatorrhea). Thus, mistakenly treating a patient with pancreatic insufficiency with PATANASE® rather than the appropriate pancreatic enzymes would result in exacerbation of the disorder, including potential hospitalization. Long term, deficiencies in nutrients could lead to malnourishment and various related maladies. Additionally, the patient would be exposed to PATANASE® side effects, including potentially nasal irritation, nasal burning, sedation and impaired taste, at normal doses. If the patient administers excessive PATANASE® doses, due to the fact that pancreatic enzymes are generally dosed after each meal and snack, the dispensing error could lead to a potential overdose of PATANASE®. Excessive sedation resulting from such overdose, without any warning, could lead to accidents while operating a car/machinery or other untoward outcomes.

In addition to the trade names discussed above, PATANASE® is also confusingly similar to the following existing trade names:

Pentasa
Pannaz

Pentasa begins with the same "P[vowel]n" sound and look as PATANASE®; it includes a middle "t"; and it has an "as" look and sound very near the end of the name. Pannaz begins with the same "Pa-" element as PATANASE®, and it ends with a "naz" element that could be readily confused with the "nase" element of PATANASE®.

If a patient mistakenly received Pentasa instead of PATANASE®, the patient would be exposed to the adverse events associated with Pentasa, including diarrhea, headache, nausea, and vomiting. Postmarketing reports associated with post-approval use of mesalamine (the active

ingredient in Pentasa) have included hepatotoxicity, including liver failure, with some cases being fatal. In addition, the patient's allergic rhinitis would be untreated.

If a patient mistakenly received PATANASE® instead of Pentasa, the patient's ulcerative colitis would be untreated. Untreated, the disease could progress, leading to more frequent or severe relapses and ultimately accelerating the potential need for colonectomy.

A mix-up in the dispensing of PATANASE® and Pannaz could result in a patient inappropriately receiving a decongestant and anticholinergic (present in Pannaz but not PATANASE®). In certain patients these ingredients could present undesirable risks.

The safety issues created by product confusion in the dispensing of drugs pursuant to oral or written prescriptions have appropriately received significant attention from FDA and are increasingly recognized as a major public health problem. Most recently, FDA, AstraZeneca, and Ortho-McNeil Neurologics have warned of drug-dispensing errors involving the three brand-name medications Toprol-XL, Topamax, and Tegretol/Tegretol-XR. AstraZeneca said it has received reports of medication errors involving Toprol-XL, its extended-release version of Toprol, a beta blocker used to treat heart failure and hypertension. The drug has been mixed up with Topamax, an Ortho-McNeil Neurologics drug, used to treat epilepsy and migraines, and Tegretol, a Novartis drug used to treat seizures and neuralgia. In some cases patients were hospitalized because of the medication errors, generally due to worsening of the underlying condition that was not treated properly as a result of the medication error. The sponsor reported that there were reports of recurrence of seizures, return of hallucinations, recurrence of hypertension and at least one suicide attempt. Most of the errors resulted from verbal and written prescriptions being incorrectly interpreted and incorrectly filled because of the similarity in the names of the drugs.

The similarities between the name PATANASE® and the other drugs discussed above appear to be at least as great as the similarities in look and/or sound that resulted in the Toprol-XL dispensing errors. Unfortunately, the Toprol-XL and related errors became apparent ***after*** the various trade names were approved and in use. In the case of PATANASE®, FDA has the ability and authority to prevent similar errors from occurring in the first instance. While the dosage form or strength of PATANASE® may not be the same as drugs with which it can be confused, this information may frequently not appear on written prescriptions or be conveyed in verbal prescriptions. FDA should not take the chance that oral or written prescriptions for PATANASE® will be confused with other drugs, or that PATANASE® will be mistakenly dispensed in response to prescriptions intended for other drugs. We respectfully submit that the FDA should not approve the proposed PATANASE® trade name for the reasons given in this petition.

C. ENVIRONMENTAL IMPACT

The requested action has no environmental impact, and therefore a claim for categorical exclusion is submitted pursuant to 21 C.F.R. § 25.31.

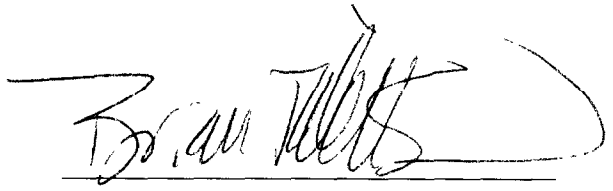
D. ECONOMIC IMPACT

Information will be submitted upon request.

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

Respectfully submitted,



Jorge Goldstein, Ph.D., Esq.
Brian J. Del Buono, Ph.D., Esq.
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Avenue, NW
Washington, DC 20005
Phone: (202) 371-2600
Fax: (202) 371-2540

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